Remarks

Reconsideration of the above-identified application is respectfully requested.

A request for continued examination was filed on April 1, 2003. In that submission, new Claims 17-32 were added to the application. In the current Office Action, the Examiner is restricting Claims 24-33 and has withdrawn them from consideration as being directed to a non-elected invention.

Claims 24-33 are directed to a method of preparing glucans. The Examiner believes that the invention in the method claims, is distinct from the claims originally presented, which relate to a cosmetic composition comprising nanoparticulate glucans. There is nothing divergent and separate from method claims 24-30 because they relate to a method of preparing nanoparticualte glucans which are the subject of the present application. The size of the glucan particles and the solubility of the glucan particles are self-evident to one skilled in the art from the intended function of the glucans as stated in the preamble of Claim 24. It is not necessary to limit Claim 24 by having the specific particle size nor solubility recited in the claim, for the claim is clearly directed to a method preparing glucans for use in a cosmetic composition. Such use would warrant a small particle size, such as a nanoparticulate form which is mentioned in the claim, as well as water solubility which would be compatible with cosmetic compositions. Clearly, Claims 24-30 are not divergent and distinct form the invention, and should be included in the prosecution of the remaining claims. Reconsideration of the Examiner's withdrawal of the Claims 24-30 is respectfully requested.

The Examiner's has requested an Abstract. An Abstract was submitted with the filing of the original application. Nevertheless, a new Abstract is being requested and one is provided on page 11.

The Examiner has objected to Claim 22 for being an improper dependent form for failing to further limit the subject matter of the previous claim, Claim 22 has been amended to further delimit Claim 17.

Claims 17-23 and 31-32 have been rejected under 37 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The term "substantially free" in Claim 17 and 31 is being objected to for the Examiner believes the term is not described in the specification, in particular, there is an objection relating to the maximum proportion or quantity of the β-(1,6) linkages that can be present in the claimed β-(1,3) glucans so that the β-(1,3) glucans can still be considered as "substantially free" of β-(1,6) linkages. Claims 17 and 31 have been amended to contain the phrase "which have intact β-(1,3) side chains and are free from repetitive β-(1,6) linkages". Support for this amendment can be found on page 2 of the specification wherein reference is made to WO 95/30022, which describes the production of glucans used in the present invention. In this disclosure, there is a limitation of up to four β-(1,6) linkages at page 4, lines 14-16. Therefore, there is an accurate description of the subject matter used in the present invention that sufficiently supports the scope of the current invention.

Claims 17-23, 31 and 32 have been rejected under 35 USC §103(a) as being unpatentable over the Kelly reference, WO-96/28476, in view of the Donzis reference, U.S. Patent No. 5,705,184. The Examiner states that the Kelly reference teaches water-soluble microparticulate glucans having predominantly β-(1,3) linkages with a lower number of β-(1,6) linkages obtained from the yeast *Saccharomyces cerevisiae*. However, the Kelly reference in fact teaches something else. The Kelly reference teaches either water-insoluble micoparticulate glucan (4-20 nm) as shown in page 4, lines 9-10 of the reference or soluble glucan made by sodium hydroxide degradation of the water-insoluble microparticulate glucan. The soluble glucans do not have a "particulate" nature. There is no disclosure of a water-soluble microparticulate glucan, as indicated by the Examiner in the Office Action. It should noted that the microparticulate glucans are by definition not water-soluble, but are suspensions of particles in water. Thus, the term "microparticulate water-soluble glucan," is a misnomer or should be regarded as a oxy-moron. If the Kelly reference teaches a glucan having predominantly β-(1,3) linkages with a lower number of β-(1,6) linkages, the teachings of the Kelly reference do not produce the same product as that claimed by applicants. Production of the glucans employed and claimed in the current application comprise a highly specific enzymatic process involving β-(1,6) endoglucanases, as described WO 95/30022. This process leads to a β-(1,3) glucan free of repetitive β-(1,6) side-chains and with fully preserved β-(1,3) side-chains. The presence of β-(1,3) side-chains contributes to the pharmaceutical benefits of the β-(1,3) glucan, as shown in WO 95/30022. The high content of this type

of side-chain is possible because the enzymatic process preserves the β-(1,3,6) branch-point linkages.

In distinction, the teachings of the Kelly reference show an acidic process which is non-specific and consequently hydrolizes all types of glucosidic linkages and glucans, also branch-point linkages like the β-(1.,3,6) linkages shown at page11, Table 1 of the reference. As a consequence, the number of the most favorable β-(1,3) side-chains is also reduced.

The Kelly reference teaches either microparticulate water-insoluble β-glucan or soluble β-glucan both with reduced content of all types of side-chains and no β-(1,6) linkages. The present invention describes and claims nanoparticles of water-soluble β-glucans, which have intact β-(1,3) side-chains and no repetitive β-(1,6) linkages.

The Donzis reference does not contribute to the combination of references. The Donzis reference discloses a purified water-insoluble β-glucan, particularly finely ground, as well as nutritional and dermatological applications of the glucan. The major intent of the teachings Donzis reference is to provide a β-glucan that does "not fall out of suspension in dermatological formulations," Donzis reference, 1 lines 50-54. Therefore, the intention of the Donzis reference is merely to solve an aesethic problem rather than improving the product's efficacy in formulations. Although the Donzis reference does point out that smaller glucan particles may be more officious as dermatological agents, at col. 3, lines 40-43, it appears that a water-soluble yeast glucan extract is regarded as the most optimal variant at col. 1, lines 37-40.

The presently claimed invention is directed towards producing clearly defined nanoparticles from a water-soluble glucan, where the nanoparticles still sustain the water-soluble characteristics of the starting material – i.e. they do not form water-insoluble microparticles, and where these nanoparticles are shown to have improved efficacy as compared to conventional pure water-soluble glucans and microparticulate glucans. A key feature of the presently claimed invention is that the water-soluble glucan in nanoparticulate form is resorbed more efficiently by skin and hair than water-soluble glucan in completely dissolved form or in microparticulate water-insoluble form.

The references, taken alone or in combination, will not lead one skilled in the art to the presently claimed invention. The test is whether the invention as a whole, in light of all the teachings of the references in their entirities, will have been obvious to one of ordinary skill in the art at the present time the invention was made. *Connell v. Sears, Roebuck & Co.* 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983). A teaching, suggestion or incentive must exist to meet the combination made by the inventor. *Interconnect Planning Corp. v Feil,* 774 F.2d 1132, 1143, 227 USPQ543, 551(Fed. Cir. 1988). The Donzis reference teaches that water-insoluble β-glucan should be ground as small as possible, but appears to hold the complete soluability is optimal. The Kelly reference provides insoluble microparticles of β-glucan (4-20 microns) and a variant of water-soluble β-glucan. A combination of these references would not leave one skilled in the art to suggest that 10-300 nm nanoparticles of soluble β-glucan are optimal for resorption in skin or hair. None of the references disclose β-glucan similar to those described and claimed by applicants.

Clearly, the references taken singly or in combination do not teach or suggest the present invention.

Since the Patent Office had failed to show a convincing suggestion or reason to combine the cited references to arrive at applicants claimed invention, a *prime facie* case obviousness has not been established by the Patent Office under 35 USC §103(a).

In view of the foregoing, applicants respectfully submit that the rejections be with withdrawn for the claims meet the requirements of 35 USC. Therefore, an early Notice of Allowance of the above-identified application is respectfully requested.

Respectfully submitted,

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Claims

1-16 (canceled)

17. (currently amended) A method for improved glucan resorption in skin or hair comprising applying to the skin or hair a cosmetic composition comprising nanoparticulate water-soluble β-(1,3)-glucans, which have intact β-(1,3) side chains and are ~~substantially~~ free from repetitive β-(1,6) linkages and have particle diameters of about 10 to 300 nm.

18. (previously presented) The method according to claim 17, wherein glucans are based on yeast of the family *Saccharomyces*.

19. (previously presented) The method according to claim 17, wherein the nanoparticulate glucans are embedded in a protective colloid.

20. (previously presented) The method according to claim 19, wherein the protective colloid is selected from the group consisting of polyvinyl alcohol and polyethylene glycol.

21. (previously presented) The method according to claim 17, wherein the glucan is present in the amount of about 0.1% to about 5% by weight relative to the cosmetic composition.

22. (currently amended) The method according to claim 17, wherein the nanoparticulate water-soluble β-(1,3)-glucans have improved resorption in skin and hair. ~~glucan resorption is for use as a skin care or hair agent, and the method comprises applying cosmetics composition to skin or hair.~~

23. (previously presented) The method according to claim 17, wherein cosmetic composition is a sun radiation protective agent.

24. (previously presented) A method of preparing glucans for use in a cosmetic composition which has improved glucan resorption comprising the steps of:

contacting glucan β-(1,3) and β-(1,6) linkages with β-(1,6) glucanases to loosen substantially all B-(1,6) linkages and reducing the size of the resulting glucans into nanoparticulate form.

25. (previously presented) The method according to claim 24, wherein the resulting glucans have a particle size ranging from about 10 to about 300 nm.

26. (previously presented) The method according to claim 24, wherein the reduction of the size of the resulting glucans into nanoparticulate form comprises the steps of:

a) dissolving the water-soluble β-(1,3) glucans under supercritical conditions

b) relaxing fluid pressure through a nozzle in a vacuum, gas or liquid, and

c) evaporating the solvent.

27. (previously presented) The method according to claim 26, wherein the conditions for dissolving the water-soluble solvent are close to critical condition.

28. (previously presented) The method according to claim 24, wherein the nanoparticulate glucans are embedded in a protective colloid.

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29. (previously presented) The method according to claim 28, wherein the protective glucans are selected from the group consisting of polyvinyl alcohol and polyethylene alcohol.

30. (previously presented) The method according to claim 26, wherein the glucan is present in the amount of about 0.1% to 5% by weight relative to the cosmetic composition.

31. (currently amended) A cosmetic composition comprising nanoparticulate water-soluble β-(1,3)-glucans, which have intact β-(1,3) side chains and are ~~substantially~~ free from repetitive β-(1,6) linkages and have particle diameters ranging in size from about 10 to 300 nm.

32. (previously presented) The cosmetic composition of claim 31, wherein the glucan is present in the amount of about 0.1% to about 5% by weight.